

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hiroaki ITO et al.

Title: A PREVENTIVE OR
THERAPEUTIC AGENT
FOR INFLAMMATORY
BOWEL DISEASE
COMPRISING IL-6
ANTAGONIST AS AN
ACTIVE INGREDIENT

U.S. Appl'n. No.: 10/677,227

Filing Date: 10/3/2003

Examiner: P. M. Mertz

Art Unit: 1646

Confirmation Number: 8597

TERMINAL DISCLAIMER

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Your Petitioner, Chugai Seiyaku Kabushiki Kaisha, having its principal place of business at 5-1, Ukimido 5-chome, Kita-ku, Tokyo, Japan 115-8543, represents that it is the owner of the entire right, title, and interest in and to the above-identified U.S. Patent Application No. 10/677,227, which is a division of U.S. Patent No. 6,723,319, granted on April 20, 2004, which issued on U.S. Patent Application No. 09/646,188, filed September 14, 2000, which is a national stage application based on PCT/JP99/01298, filed March 16, 1999, by virtue of an Assignment

filed and recorded on September 14, 2000, on Reel/Frame 011158/0971, in the United States Patent and Trademark Office, a copy of which is attached hereto as APPENDIX A.

Your Petitioner, Chugai Seiyaku Kabushiki Kaisha, hereby disclaims the terminal part of the term of any patent granted on the above identified patent application which would extend beyond the full statutory term, as shortened by any terminal disclaimer, of U.S. Patent 6,723,319, and hereby agrees that any patent so granted on the above identified patent application shall be enforceable only for and during such period that the legal title to U.S. Patent 6,723,319 shall be the same as the legal title to any patent granted on the above identified patent application, this agreement to run with any patent granted on the above identified patent application and to be binding upon the grantee, its successors or assigns.

In making the above disclaimer, Petitioner does not disclaim any terminal part of any patent granted on the above identified patent application, prior to the full statutory term of U.S. Patent 6,723,319, as defined in 35 U.S.C. §§154-156 and 173, in the event that U.S. Patent 6,723,319 expires for failure to pay a maintenance fee, is held unenforceable or is found invalid in a final judgment by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR §1.321(a), has all claims canceled by a reexamination certificate or as a result of an interference proceeding, or is otherwise not deemed to provide the rights conveyed by 35 USC §154, prior to the full statutory term of U.S. Patent 6,723,319 as defined in 35 USC §§154-156 and 173, except for the separation of legal title stated above. Further, Petitioner does not disclaim any terminal part of a patent granted on the above identified patent application that would extend beyond the present termination of U.S. Patent 6,723,319, in the event that such present term is extended by virtue of compliance with the conditions for term extension of any present or future patent term extension provisions of the patent law, including but not limited to 35 U.S.C. §§155, 155A or 156, and without waiving Petitioner's right to extend the term of a patent granted on the above identified patent application to the extent provided by law.

The undersigned, being the Attorney of Record for the above identified patent application, and duly authorized to act on behalf of Petitioner, certifies that he has reviewed the Assignments attached as APPENDIX A, and to the best of his knowledge and belief, legal title to the above identified U.S. Patent 6,723,319 and its application rests with Petitioners, Chugai Seiyaku Kabushiki Kaisha. The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing therefrom.

Respectfully submitted,

Date June 4, 2007

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By: Harold C. Wegner, Esq.
Harold C. Wegner
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HCW:SBM:ARSC:kdm

Attachment: APPENDIX A - Assignment



HCW
UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20591

DECEMBER 11, 2000

PTAS

53466/281

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RECORDATION DATE: 09/14/2000

REEL/FRAME: 011158/0971

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BRIEF: ASSIGNMENT OF ASSIGNEE'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNEE:
ITO, MIROAKI

DOC DATE: 09/04/2000

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DOC DATE: 09/04/2000

ASSIGNEE:
KISHIMOTO, TADAMITSU

DOC DATE: 09/04/2000

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SERIAL NUMBER: 09646188
PATENT NUMBER:

FILING DATE: 09/14/2000
ISSUE DATE:

KIMBERLY WHITE, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

U.S. ASSIGNMENT

36 CONSIDERATION of the sum of One Dollar (\$1.00), and of other good and valuable consideration just to the undersigned investor(s) (hereinafter "ASSIGNOR") by

Client
Assistants
Name(s)
Address(es)

11. CRUCIAL SETIYNU KARUSI XI KALISTI

3-1, Ueda 3-chome, Taito-ku, Tokyo 115-8543, Japan

21 *Macmillan's Magazine*

3-5-11, Nakano-cho, Tsurubayashi-ku, Osaka 584-0021, Japan

Code of
Conduct

(hereinafter "ASSIGNER"), the receipt of which is hereby acknowledged, the undersigned ASSIGNEE hereby sells, assigns and transfers to ASSIGNEE the entire and exclusive right, title and interest in the invention entitled

A PREVENTIVE OR THERAPEUTIC AGENT FOR INFLAMMATORY BOWEL DISEASE COMPRISING
IL-6 ANTAGONIST AS AN ACTIVE INGREDIENT

relating to International Patent Application PCT/US 99/01296, and/or for which application for Letters Patent of the United States was prosecuted on even date herewith or, if not so prosecuted, was:

Classes
of exercises
of application
of the
concerned

(4) Executed on _____
(5) Filed on _____
Serial No. _____

_____ is readily authorized to insert in (b) the specified data, when known.

and to said application and all Letters Patent(s) of the United States granted on said application and any continuation, division, renewal, substitute, revised or reexamination application based thereon, for the full term or terms for which the said Letters Patent(s) may be granted and including any extensions thereof (collectively, hereinafter, "said application(s) and Letters Patent(s)").

The ASSIGNEE agrees, when requested by said ASSIGNEE and without charge to but at the expense of said ASSIGNEE, to do all acts which the ASSIGNEE may deem necessary, desirable or expedient, for securing, maintaining and enforcing protection for said invention, including in the preparation and presentation of said application(s) and the issuance of said Letters Patent(s), in any interference, release, reexamination, or public use proceeding, and in any litigation or other legal proceeding which may arise or be declared as relates to same, such acts to include but not be limited to executing all papers, including separate assignments and declarations, taking all rightful oaths, providing sworn testimony, and obtaining and producing evidence.

BY WITNESS WHEREUPON, the undersigned (several) has (have) affixed his/her signature:

• Hiroaki Ito Hiroaki Ito September 4, 2000
• Mitsuru Yamamoto Mitsuru Yamamoto September 4, 2000
• Fadumitsu Kishimoto Fadumitsu Kishimoto September 4, 2000